

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

5:16M 1003

IN THE MATTER OF THE
ADMINISTRATIVE INSPECTION OF:

Precision Herbs
9804 Township Road 89
Killbuck, Ohio 44637

9227 Township Road 82
Millersburg, Ohio 44654

)
) CASE NO.
)
) MAGISTRATE JUDGE BURKE
)
) APPLICATION FOR EX PARTE
) ADMINISTRATIVE INSPECTION
) WARRANT
)

The United States of America, by and through the undersigned counsel, on behalf of the United States Food and Drug Administration ("FDA"), United States Department of Health and Human Services, hereby seeks an administrative inspection warrant under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 374, to enter and inspect Precision Herbs, located at 9804 Township Road 89, Killbuck, Ohio, and 9227 Township Road 82, Millersburg, Ohio, at reasonable times during ordinary business hours to access, copy, and verify the records to which it is entitled under the Act for the firm's devices, drugs, and foods (dietary supplements). Such records include, but are not limited to: (1) records to evaluate the devices that Precision Herbs sells: to determine whether the firm is complying with statutory requirements, such as registration and listing requirements, premarket notification requirements, and the Quality System Regulation; to ensure that the firm is not marketing adulterated or misbranded devices; and to evaluate device labeling, manufacturing, and distribution records to ensure that only devices that have received FDA premarket approval or clearance for their intended uses are distributed in interstate commerce; (2) records to evaluate the drugs that Precision Herbs sells: to determine whether the firm is complying with statutory requirements, such as drug registration and listing requirements, new drug approval requirements, and the

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current good manufacture practice (CGMP) requirements for drugs; to ensure that the firm is not marketing adulterated or misbranded drugs; and to evaluate drug labeling, manufacturing, and distribution records to ensure that only drugs that have received FDA approval for their intended uses are distributed in interstate commerce; and (3) records to evaluate the dietary supplements that Precision Herbs sells: to determine whether the firm is complying with statutory requirements such as the food registration requirements, dietary supplement CGMP regulations, and labeling requirements; and to ensure that the firm is not marketing adulterated or misbranded dietary supplements.

Precision Herbs has previously refused to permit FDA to inspect its facility in Killbuck, Ohio, and has refused access to its records, necessitating this application, despite statutory authorization for such inspections under 21 U.S.C. § 374. In support of its Application for *Ex Parte* Administrative Inspection Warrant, the United States represents as follows:

1. The Application for *Ex Parte* Administrative Inspection Warrant arises from Precision Herbs's refusal to permit investigators from the FDA to enter and inspect a Precision Herbs facility in which devices, drugs, and foods (dietary supplements) are manufactured, processed, packed, and/or held for introduction into interstate commerce or after such introduction.
2. Precision Herbs manufactures, processes, packs, and/or holds devices, drugs, and foods (dietary supplements), which are sold to customers in interstate commerce throughout the United States and worldwide. Affidavit of Benjamin J. Dastoli ("Dastoli Aff.") ¶¶ 2, 4, 6, 15-17.
3. Precision Herbs manufactures, processes, packs, holds and/or distributes devices that it claims treat various diseases and conditions, such as bacteria, viruses, toxins, parasites, and kidney and liver disease. *Id.* ¶ 2. Under the Act, these products are devices because they are

“intended for use in the . . . cure, mitigation, treatment, or prevention of disease” or are “intended to affect the structure or any function of the body,” and they “do[] not achieve [their] primary intended purposes through chemical action within or on the body” and are “not dependent upon being metabolized for the achievement of [their] primary intended purposes.” 21 U.S.C.

§ 321(h); Dastoli Aff. ¶ 2. Precision Herbs is not registered with FDA as a device manufacturer and there are no FDA-approved or cleared applications permitting the marketing of Precision Herbs’s devices. Dastoli Aff. ¶ 3.

4. Precision Herbs manufactures, processes, packs, holds and/or distributes drugs that it claims treat various diseases and conditions, including but not limited to tumors, carcinogenic chemicals, and cancer. *Id.* ¶ 4. Under the Act, these products are drugs because they are “intended for use in the . . . cure, mitigation, treatment, or prevention of disease” or are “intended to affect the structure or any function of the body.” 21 U.S.C. §§ 321(g)(1)(B) and (C); Dastoli Aff. ¶ 4. The articles are also “new drugs,” as defined in 21 U.S.C. § 321(p), because they are not generally recognized as safe and effective for their labeled uses. Dastoli Aff. ¶ 4. Precision Herbs is not registered with FDA as a drug manufacturer and there are no FDA-approved drug applications permitting the marketing of Precision Herbs’s drugs. *Id.* ¶ 5.

5. Precision Herbs manufactures, processes, packs, holds and/or distributes dietary supplements that contain at least one dietary ingredient as that term is described in 21 U.S.C. § 321(ff)(1); Dastoli Aff. ¶ 6. These products are deemed to be “food” under the Act, 21 U.S.C. § 321(ff). *Id.* Precision Herbs is not registered with FDA as a food facility. *Id.* ¶ 7.

6. Precision Herbs previously was co-owned by Dr. James Overman and his wife Sharon Overman. *Id.* ¶ 1. Dr. Overman passed away on May 18, 2012, and Precision Herbs is now owned and operated by Sharon Overman and Dr. Eric Pierce, who allegedly helped Dr.

Overman formulate Precision Herbs's products. *Id.*

7. FDA first inspected Precision Herbs's facility located at 9804 Township Road 89, Killbuck, Ohio, from September 24 - October 14, 2009 (hereafter, 2009 Inspection), in follow-up to a Warning Letter FDA issued on May 21, 2008, citing the firm for selling unapproved new drugs and misbranded drugs (hereafter, 2008 Warning Letter). *Id.* ¶¶ 9, 11. During the 2009 Inspection, FDA investigators inquired about Overman's Healthy Choices, Inc., located at 9227 Township Road 82, Millersburg, Ohio, a second location to which the 2008 Warning Letter was addressed. *Id.* ¶ 11. Dr. Overman told the FDA investigators that he saw clients and sold herbal products and devices at that location. *Id.* On October 1, 2009, during the 2009 Inspection, Dr. Overman told the investigators that he would not answer any more oral questions or provide any records without a written request, and he sent numerous letters objecting to FDA's inspection. *Id.* ¶¶ 11-12. After FDA sent a second Warning Letter dated December 1, 2011, citing Precision Herbs for marketing adulterated and misbranded devices, Dr. Overman wrote FDA and said that Precision Herbs was a private membership association over which FDA had no jurisdiction. *Id.* ¶¶ 13-14.

8. When FDA attempted to inspect Precision Herbs's facility at 9804 Township Road 89, Killbuck, Ohio, on March 23, 2015, Eric Pierce refused to permit FDA to inspect, claiming Precision Herbs was a private organization protected from inspection by the Constitution. *Id.* ¶¶ 18-19. When FDA investigators left the Killbuck, Ohio facility, they drove to the 9227 Township Road 82, Millersburg, Ohio location. *Id.* ¶ 20. The investigators observed a sign that read "Original Design Wellness Center" and noted several cars in the parking lot, including the vehicle that Mr. Pierce had been driving. *Id.* The FDA investigators did not attempt to enter or inspect the facility located at 9227 Township Road 92, Millersburg, Ohio.

Correspondence FDA received from Mr. Pierce following the attempted inspection at the Killbuck, Ohio location identified the 9227 Township Road 92, Millersburg, Ohio address as the “Organization Head Office” for Precision Herbs. *Id.* ¶ 21.

Regulation of the Device, Drug, and Food (Including Dietary Supplement) Industries

9. The device, drug, and food (including dietary supplement) industries are pervasively regulated. *See United States v. Jamieson-McKames Pharms., Inc.*, 651 F.2d 532, 537 (8th Cir. 1981) (“[V]irtually every phase of the drug industry is heavily regulated, from packaging, labeling, and certification of expiration dates, to prior FDA approval before new drugs can be marketed. The regulatory burdens on the drug-manufacturing industry are weighty, and that weight indicates that the drug manufacturer accepts the burdens as well as the benefits of the business and consents to the regulations placed on him.”) (internal footnotes omitted); *United States v. Del Campo Baking Mfg. Co.*, 345 F. Supp. 1371, 1377 (D. Del. 1972) (“Defendants’ business of manufacturing, processing, packing and distributing food products for introduction into interstate commerce is as ‘pervasively regulated’ by the [Act] and the regulations promulgated thereunder, as if it were federally licensed.”); *cf. Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 344-46 (2001) (setting forth FDA’s comprehensive regulatory authority over medical devices under the Act, as amended by the Medical Device Amendments of 1976).

10. The Act’s requirements for the device industry are found, *inter alia*, in 21 U.S.C. §§ 321(h), 351, 352, 360, 360c, 360e, 360f, 360i, and 360j. Manufacturers of devices intended for human use are required to establish, maintain, and provide certain records to FDA, so FDA can ensure that the devices are not adulterated, misbranded, or otherwise not safe or effective. *See* 21 U.S.C. § 360i(a). Such manufacturers must also use methods and controls that conform

to the Quality System Regulation, 21 C.F.R. Part 820, which contains the current good manufacturing practice (CGMP) requirements for devices. *See* 21 U.S.C. § 360j(f)(1)(A). A device that is introduced into interstate commerce without premarket approval as required by the Act, or that is not manufactured in accordance with CGMP, is deemed adulterated. *See* 21 U.S.C. §§ 351(f)(1)(B), 351(h). Device manufacturers are also subject to the Establishment Registration and Device Listing For Manufacturers and Initial Importers of Devices, 21 C.F.R. Part 807. A device that is manufactured in an establishment that is not registered under the Act, or a device for which premarket notification was not provided as required by the Act, is deemed misbranded. *See* 21 U.S.C. § 352(o).

11. The Act's requirements for the drug industry are found, *inter alia*, at 21 U.S.C. §§ 321(g), (p), 351, 352, 355, 360. Under 21 U.S.C. §§ 331(d) and 355(a), a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved new drug application is in effect for such drug or an investigational new drug application is in effect to permit such drug to be distributed for research purposes. Drug manufacturers must also conform to the CGMP requirements for drugs. 21 C.F.R. Parts 210 and 211. A drug that is not manufactured in accordance with CGMP is deemed adulterated. *See* 21 U.S.C. § 351(a)(2)(B). Drug manufacturers must also register and list with FDA. 21 C.F.R. Part 207. A drug that is manufactured in an establishment that is not registered under the Act is deemed misbranded. *See* 21 U.S.C. § 352(o).

12. The Act's requirements for the food industry are found, *inter alia*, at 21 U.S.C. §§ 321(f), (ff), 342, 343, and 350d. Food (including dietary supplement) facilities must be registered with FDA. 21 U.S.C. § 350d; 21 C.F.R. § 1.227(b)(4)(ii). There are specific labeling requirements for food, including those that address acceptable health claims, *see* 21 C.F.R. Part

101; dietary supplements that are improperly labeled are deemed to be misbranded. 21 U.S.C. §§ 343(r)-(s). Dietary supplement manufacturers must also follow the CGMP regulations for dietary supplements. 21 C.F.R. Part 111. A dietary supplement that is not manufactured in accordance with CGMP is deemed adulterated. *See* 21 U.S.C. § 342(g).

FDA Has the Authority to Inspect Device, Drug, and Food (Including Dietary Supplement) Manufacturers

13. In accordance with its public health mission, FDA has the authority under the Act to enter and inspect any establishment in which devices, drugs, and/or food (including dietary supplements) are manufactured, processed, packed, or held, for introduction into interstate commerce or after introduction of such devices, drugs, or food (or any of their components) into interstate commerce, or to enter and inspect any vehicle being used to transport or hold such devices, drugs, or food in interstate commerce. 21 U.S.C. § 374(a)(1). FDA's inspectional authority extends to factories, warehouses, establishments, or vehicles and "all pertinent equipment, finished and unfinished materials, containers, and labeling therein." *Id.*; *see Jamieson-McKames Pharms., Inc.*, 651 F.2d at 537-39.

14. The Act authorizes a broader inspection of "all things therein (including records, files, papers, processes, controls, and facilities)" bearing on violation of the Act "[i]n the case of any . . . establishment . . . in which prescription drugs [or] non-prescription drugs intended for human use . . . are manufactured, processed, packed, or held." 21 U.S.C. § 374(a)(1). The Act's implementing regulations provide for FDA's inspection and copying of records relating to drugs. *See, e.g.*, 21 C.F.R. §§ 211.180(c) ("All records required under [the Current Good Manufacturing Practice (CGMP) requirements for drugs], or copies of such records, shall be readily available for authorized inspection . . ."). Similarly for devices, 21 C.F.R. § 820.180 states that "[a]ll records required by [the device Quality System Regulations] shall be maintained at the

manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of FDA designated to perform inspections. Such records, including those not stored at the inspected establishment, shall be made readily available for review and copying by FDA employee(s).” And for dietary supplements, 21 C.F.R. § 111.610(a) states that “[y]ou must have all records required under [the CGMP requirements for dietary supplements], or copies of such records, readily available during the retention period for inspection and copying by FDA when requested.”

15. Under basic rules of statutory construction and applying the reasonableness standard, 21 U.S.C. § 374 clearly grants FDA the authority to use a wide range of investigational tools, including photocopying records and taking photographs and video recordings, in carrying out its statutory mandate to protect the public health. *See Dow Chem. Co. v. United States*, 476 U.S. 227, 233 (1986) (explaining that investigative authority Congress vested with agency “carries with it all the modes of inquiry and investigation traditionally employed or useful to execute the authority granted,” including photography); *see also United States v. Chung’s Products LP*, 941 F. Supp. 2d 770, 777 (S.D. Tex. 2013) (noting improper refusals to permit photography during an FDA inspection); *United States v. Acri Wholesale Grocery Co.*, 409 F. Supp. 529, 532-33 (D. Iowa 1976) (photographing by FDA investigator of warehouse conditions was not unreasonable; even if such photographing was a search and seizure, once the inspection’s validity was established, the propriety of photographic search was coextensive with the validity of the inspection); *United States v. Gel Spice Co.*, 601 F. Supp. 1214, 1220 (E.D.N.Y.), *aff’d* 773 F.2d 427 (2d Cir. 1985) (photographs were lawfully taken during FDA inspection). As the Supreme Court has instructed, “[c]ommon sense and ordinary human experience” must guide the construction of investigatory authority. *Dow Chem.*, 476 U.S. at 233

(“When Congress invests an agency with enforcement and investigatory authority, it is not necessary to identify explicitly each and every technique that may be used in the course of executing the statutory mission.”).

16. FDA also has the authority to inspect an establishment to determine whether it has jurisdiction. *See, e.g., Okla. Press Publ'g Co. v. Walling*, 327 U.S. 186, 214 (1946) (enforcing administrative subpoenas for records to determine whether a business was covered by the Fair Labor Standards Act); *ICC v. Peninsula Shippers Ass'n*, 789 F.2d 1401, 1402-03 (9th Cir. 1986) (“[A]n agency has jurisdiction to determine jurisdiction by summary procedures As long as the agency arguably has jurisdiction to inspect, questions of jurisdiction such as whether the business was in fact engaged in interstate commerce . . . or whether the business has engaged in [a regulated activity] are to be determined in the first instance by summary inspection procedures and need not be first litigated in court.” (internal quotations marks omitted)).

17. An inspection performed pursuant to 21 U.S.C. § 374 does not require an inspection warrant. *Wedgewood Vill. Pharms, Inc. v. United States*, 421 F.3d 263, 266 (3d Cir. 2005); *United States v. Argent Chem. Labs., Inc.*, 93 F.3d 572, 577-78 (9th Cir. 1996). If a party does not consent to an inspection, however, courts have held that “FDA [is] obliged to obtain an administrative warrant in order to effect the inspection.” *Jamieson-McKames Pharms., Inc.*, 651 F.2d at 540; *see also United States v. Biswell*, 406 U.S. 311, 316 (1972) (warrantless search of pervasively regulated gun dealership under Gun Control Act does not violate the Fourth Amendment); *Colonnade Catering Corp. v. United States*, 397 U.S. 72, 77 (1970) (although the liquor industry was long subject to close supervision and inspection, forcible entry was not permitted without a warrant).

Precision Herbs Refused to Permit FDA Representatives to Inspect, Access, Copy, and Verify Records, Based On A Meritless “Private Membership Association” Theory

18. FDA investigators attempted to inspect Precision Herbs’s Killbuck, Ohio facility in March 2015; however, Mr. Eric Pierce refused to provide them with access to the facility. Dastoli Aff. ¶¶ 18-19. Mr. Pierce later provided the investigators with documents stating that Precision Herbs is a private membership association over which FDA allegedly lacks jurisdiction. *Id.* ¶ 19. Even if Precision Herbs were a private membership association, courts have rejected the proposition that it would not be subject to FDA regulation, including inspection. There is no legal basis for withholding information from FDA, for at least three reasons.

19. *First*, the Act authorizes FDA to inspect “any ... establishment in which food, drugs, [or] devices ... are manufactured, processed, packed, or held, for introduction into interstate commerce.” 21 U.S.C. § 374(a)(1)(A). The Act does not recognize an exception to FDA’s inspection authority, nor to the Act’s clear prohibition on the sale of adulterated or misbranded devices, drugs, and dietary supplements and unapproved new drugs, based on the nature of the contractual relationship between the manufacturer, distributor, and end user. Such arguments have been rejected by several district courts and just recently by the Eighth Circuit Court of Appeals. *Lytle v. HHS*, 612 F. App’x 861, 861-62 (8th Cir. 2015) (rejecting the argument that FDA lacks regulatory jurisdiction over devices distributed in non-commercial transactions through private membership associations); *United States v. Cole*, 84 F. Supp. 3d 1159, 1170 (D. Or. Feb. 5, 2015) (finding defendant’s plan to create private membership association to continue providing misbranded and adulterated product showed necessity for injunction to prevent future Act violations); *United States v. Allgyer*, No. 11–02651, 2012 WL 355261, at *4, n.15 (E.D. Pa. Feb. 3, 2012) (flatly rejecting a party’s so-called “private

membership” agreement as “merely a subterfuge” to unlawfully evade FDA regulation); *see also United States v. Travia*, 180 F. Supp. 2d 115, 120-21 (D.D.C. 2001) (rejecting argument that the Act does not apply to the “private behavior.”).

20. *Second*, by deciding to operate in heavily-regulated industries such as the device, drug, and food industries, Precision Herbs has chosen to subject itself to government regulation, including FDA’s authority to inspect and collect records under the Act. *Wedgewood Vill. Pharms, Inc.*, 421 F.3d at 274 (“As the Supreme Court has explained: ‘when a dealer chooses to engage in [a] pervasively regulated business . . . he does so with the knowledge that his business records . . . will be subject to effective inspection.’”); *Argent Chem. Labs., Inc.*, 93 F.3d at 574-76; *Jamieson-McKames Pharms., Inc.*, 651 F.2d at 538-42.

21. *Third*, an individual cannot exempt himself from the reach of federal law through the use of private contracts; such attempts run afoul of well-established law that “a contract entered in violation of federal statutory or regulatory law is unenforceable.” *Resolution Trust Corp. v. Home Sav. of Am.*, 946 F.2d 93, 96 (8th Cir. 1991); *see also, Jackson Purchase Rural Elec. Co-op. Ass’n v. Local Union 816, Int’l Bhd. of Elec. Workers*, 646 F.2d 264, 267 (6th Cir. 1981) (“a promise is unenforceable if legislation so provides, or if the interest in enforcement is clearly outweighed by the public policy against enforcement.”); *United States v. Luxury Blankets, Inc.*, 762 F.2d 1012 (table), 1985 WL 13194, at *3 (6th Cir. 1985) (“[I]llegal contracts are unenforceable only ‘where (1) a statute explicitly provides that contracts contravening it are void or (2) where ‘the interest in [the contract’s] enforcement is clearly outweighed in the circumstances by a public policy against the enforcement of such terms.’”).

22. In sum, the statute provides no exception for private membership organizations, Precision Herbs has chosen to operate in pervasively-regulated industries (selling devices, drugs,

and foods), and Precision Herbs cannot contractually exempt itself from federal law. It is therefore subject to the Act, including its inspection and record-keeping requirements. *Lytle*, 612 F. App'x at 861-62; *Cole*, 84 F. Supp. 3d at 1170; *Allgyer*, 2012 WL 355261, at *4, n.15; see also *Biswell*, 406 U.S. at 316 (“when a dealer chooses to engage in [a] pervasively regulated business and to accept a federal license, he does so with the knowledge that his business records, [and stock] will be subject to effective inspection”); *Jamieson-McKames Pharms.*, 651 F.2d at 537 (“when an entrepreneur embarks on [the drug manufacturing] business, he has chosen to subject himself to a full arsenal of governmental regulation.”).

A Warrant Is Needed for a Complete and Effective Inspection


23. FDA is charged with protecting the public health by ensuring, among other things, that “there is reasonable assurance of the safety and effectiveness of devices intended for human use;” “human [] drugs are safe and effective;” and “foods are safe, wholesome, sanitary, and properly labeled.” 21 U.S.C. § 393(b)(2)(A)-(C). To carry out its public health mission, FDA must be able to: (1) evaluate the devices that Precision Herbs sells and determine whether the firm is complying with registration and listing requirements, premarket notification requirements, and the Quality System Regulation, and determine whether Precision Herbs’s devices are being lawfully marketed under the Act. In addition, FDA must be able to evaluate device labeling, manufacturing, and distribution records to ensure that only devices that have received FDA premarket approval or clearance for their intended uses are distributed in interstate commerce; (2) evaluate the drugs that Precision Herbs sells and determine whether the firm is complying with drug registration and listing, drug approval, and CGMP requirements for drugs, and determine whether Precision Herbs’s drugs are being lawfully marketed under the Act. In addition, FDA must be able to evaluate drug labeling, manufacturing, and distribution records to

ensure that only drugs that have received FDA approval for their intended uses are distributed in interstate commerce; and (3) evaluate the dietary supplements that Precision Herbs sells and determine whether the firm is complying with the food registration requirements and the dietary supplement CGMP regulations.

24. Such administrative inspection warrants may be obtained on an *ex parte* basis. *In the Matter of Establishment Inspection of Wedgewood Village Pharmacy, Inc.*, 270 F. Supp. 2d 525, 552 (D.N.J. 2003) (“The *ex parte* application serves to allow for maintenance of the status quo in this very serious of public health areas.”).

25. A return will be made to this Court within ten (10) business days after the completion of the inspections.

Respectfully submitted,
STEVEN M. DETTELBACH
United States Attorney
Northern District of Ohio


STEVEN J. PAFFILAS (0037376)
ALEJANDRO A. ABREU (0089477)
Assistant United States Attorneys
United States Court House
801 West Superior Avenue
Suite 400
Cleveland, OH 44113-1852
(Phone) 216-622-3698
(Phone) 216-622-3620
(Fax) 216-522-2404
Steven.Paffilas@usdoj.gov
Alejandro.A.Abreu@usdoj.gov

OF COUNSEL:

WILLIAM B. SCHULTZ
General Counsel

ELIZABETH H. DICKINSON
Chief Counsel
Food and Drug Division

ANNAMARIE KEMPIC
Deputy Chief Counsel, Litigation

MARCI B. NORTON
Senior Counsel
United States Department of Health and Human Services
Office of the General Counsel
White Oak Bldg. 31, Room 4510
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002
(301) 796-8580